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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/663,506	09/15/2003	Muhammad Ashraf	AM-101106US	1850

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EXAMINER	
CARTER, KENDRA D	

ART UNIT	PAPER NUMBER
1627	

NOTIFICATION DATE	DELIVERY MODE
07/07/2010	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

docketing@howsonandhowson.com

Office Action Summary	Application No.	Applicant(s)	
	10/663,506	ASHRAF ET AL.	
	Examiner	Art Unit	
	KENDRA D. CARTER	1627	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *18 March 2010*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *10-19 and 21-27* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *10-19 and 21-27* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *3/18/10*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application.
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after allowance or after an Office action under *Ex Parte Quayle*, 25 USPQ 74, 453 O.G. 213 (Comm'r Pat. 1935). Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, prosecution in this application has been reopened pursuant to 37 CFR 1.114. Applicant's submission filed on March 18, 2010 has been entered.

The Examiner acknowledges the applicant's remarks and terminal disclosure of US Patent No. 7,271,177 filed March 15, 20010 made to the Allowance filed December 22, 2009. Claims 10-19 and 21-27 are pending. Claims 21-27 are new. Claims 1-9 and 20 are cancelled.

The Examiner would like to note that the inclusion of the Hanabusa et al. reference in the reasons for allowance is a clerical error and should be omitted.

Upon further consideration and search the new rejections are made below.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

(1) Claims 10-19 and 21-27 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 7-8 and 11 of copending Application No. 11/030,685 in view of Azrolan et al. (US 2002/0013335 A1) and Dukart et al. (US 2002/0091137 A1). This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Although the conflicting claims are not identical, they are not patentably distinct from each other for the following reasons.

The U.S. Application 11/030,685 teaches a composition comprising micronized CCI-779, surfactant, filler/binder, disintegrant (see claims 1 and 7), one or more antioxidants, a chelating agent, and/or a pH modifier (see claim 11). The surfactant is sodium lauryl sulfate (see claim 8). An oral CCI-779 dosing unit comprises citric acid at 0.08% w/w, BHT at 0.05% w/w, BHA at 0.022% w/w (see claim 23), and 2% w/w hydroxypropylmethylcellulose (see claim 26). The dosing unit is selected from the group consisting of a tablet and a capsule (see claim 27).

The U.S. Application 11/030,685 does not teach the specific wordage "water soluble polymer" or a composition comprising a oral composition in a granulation form. Additionally, the specific water soluble polymer, polyvinylpyrrolidone (PVP) and its amounts are not disclosed.

Azrolan et al. teaches oral formulations of 42-ester with 3-hydroxy-2-(hydroxymethyl)-2-methylpropionic acid (see claim 5 and page 4, column 1, paragraph 26, lines 1-2) comprising for useful tablet formulations sodium lauryl sulfate, polyvinylpyrrolidone, poloxamer 188, sodium dodecyl sulfate, and wet or dry granulation (see page 4, column 1, paragraph 26, lines 10, 11, 16-18, 25, column 2, line 1). For suspensions as a free base or pharmacologically acceptable salt hydroxyl-propyl-

cellulose is used (see page 4, column 2, paragraph 28, lines 2-6). For sterile aqueous solutions or dispersions and sterile powders, polyethylene glycol, water, ethanol, and vegetable oils are used (see page 4, column 2, paragraph 29, lines 2-4 and 10-12).

Dukart et al. teach a formulation and method of treatment comprising CCI-779 (i.e. 42-ester with 3-hydroxy-2-(hydroxymethyl)-2-methylpropionic acid) that can be in a tablet form made by conventional compression, wet granulation or dry granulation methods (see abstract and paragraph 38). The formulations can also be administered parenterally (see paragraph 40)

One having ordinary skill in the art would find it obvious to formulate a pharmaceutical composition and that the tablet was in granular form because Dukart et al. teach that formulations comprising CCI-779 can be made formulated in a tablet form made by conventional compression, wet granulation or dry granulation. Thus, it is within the skill of the art to make a dry granulation tablet of CCI-779.

One having ordinary skill in the art would find it obvious to formulate a pharmaceutical composition comprising a water soluble polymer because hydroxypropylmethylcellulose (see claim 26) is a water soluble polymer. "Products of identical chemical composition can not have mutually exclusive properties." A chemical composition and its properties are inseparable. Therefore, if the prior art teaches the

identical chemical structure, the properties applicant discloses and/or claims are necessarily present. *In re Spada*, 911 F. 2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990).

One having ordinary skill in the art would find it obvious to formulate a pharmaceutical composition comprising polyvinylpyrrolidone (PVP) because Azrolan et al. teaches a composition comprising 42-ester with 3-hydroxy-2-(hydroxymethyl)-2-methylpropionic acid (see claim 5 and page 4, column 1, paragraph 26, lines 1-2) comprising for useful tablet formulations polyvinylpyrrolidone (see page 4, column 1, paragraph 26, lines 10, 11, 16-18, 25, column 2, line 1). Thus, the specific water soluble polymer, PVP, has been taught in combination with the Applicant's compound in a solid preparation.

In regards to the range of the PVP, it is within the skill of the art to adjust concentrations to obtain desired characteristics. Additionally, the water soluble polymer, hydroxypropylmethylcellulose is in the composition in about 2% w/w (see claim 26). Thus, it would be obvious to comprise the composition with the same amounts of a different water soluble polymer. Since there are no reasons disclosed why the particular range of about 5% to about 20% wt/wt gives results that produce unexpected results, then the ranges of the water soluble polymer are obvious to one skilled in the art to obtain.

(2) Claims 10-19 and 21-27 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 13-16 of copending Application No. 10/626,943. This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Although the conflicting claims are not identical, they are not patentably distinct from each other for the following reasons.

The U.S. Application 10/626,943 teaches a parenteral formulation (see claim 12) which comprises an antioxidant, propylene glycol (see claim 15), citric acid (see claim 14), a surfactant (see claim 12), ethoxylated vegetable oil, and polyoxyethylene-polyoxypropylene block copolymers (see claim 16). The antioxidant comprises from about 0.0005 to 0.5% w/v of the formulation.

The U.S. Application 10/626,943 discloses range of the antibiotic is w/v, whereas the applicant discloses the antibiotic range in wt/wt. The different measurements are viewed as the same to one ordinarily skilled in the art. The w/v measurements are taken in regards to the co-solvent concentrate, which is water (see claim 15). Since water has a density of 1 g/mL, and the weight of the applicant's composition is taken as a whole (i.e. 1), then the measurements are virtually the same.

The U.S. Application 11/030,685 does not teach the specific wordage "water soluble polymer" or a composition comprising a solid granulation. Additionally, the ranges of the water soluble polymer and surfactant are not disclosed.

Azrolan et al. teaches oral formulations of 42-ester with 3-hydroxy-2-(hydroxymethyl)-2-methylpropionic acid (see claim 5 and page 4, column 1, paragraph 26, lines 1-2) comprising for useful tablet formulations sodium lauryl sulfate, polyvinylpyrrolidone, poloxamer 188, sodium dodecyl sulfate, and wet or dry granulation (see page 4, column 1, paragraph 26, lines 10, 11, 16-18, 25, column 2, line 1). For suspensions as a free base or pharmacologically acceptable salt hydroxyl-propyl-cellulose is used (see page 4, column 2, paragraph 28, lines 2-6). For sterile aqueous solutions or dispersions and sterile powders, polyethylene glycol, water, ethanol, and vegetable oils are used (see page 4, column 2, paragraph 29, lines 2-4 and 10-12).

Dukart et al. teach a formulation and method of treatment comprising CCI-779 (i.e. 42-ester with 3-hydroxy-2-(hydroxymethyl)-2-methylpropionic acid) that can be in a tablet form made by conventional compression, wet granulation or dry granulation methods (see abstract and paragraph 38). The formulations can also be administered parenterally (see paragraph 40)

One having ordinary skill in the art would find it obvious to formulate a pharmaceutical composition and an oral formulation in granular form because Dukart et

al. teach that formulations comprising CCI-779 can be made formulated parenterally or in a tablet form. Thus, it is within the skill of the art to make a dry granulation tablet or parental form of CCI-779.

Although citric acid is disclosed as an antibiotic and polyethylene glycol is disclosed as a dilute solvent, a chemical composition and its properties are inseparable. "Products of identical chemical composition can not have mutually exclusive properties." Therefore, if the prior art teaches the identical chemical structure, the properties applicant discloses and/or claims are necessarily present. *In re Spada*, 911 F. 2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990).

In regards to the range of the water soluble polymer and surfactant in the composition, it is within the skill of the art to adjust concentrations to obtain desired characteristics. Since there are no reasons disclosed why the particular range of about 1% to about 40%, and about 1% to about 8% gives results that produce unexpected results, then the ranges of the antioxidant, water soluble polymer and surfactant are obvious to one skilled in the art to obtain.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to KENDRA D. CARTER whose telephone number is (571)272-9034. The examiner can normally be reached on 9:00 am - 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on (571) 272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Shengjun Wang/
Primary Examiner, Art Unit 1627

/Kendra D Carter/
Examiner, Art Unit 1627